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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,069	01/29/2002	Alejandro Abuin	LEX-0305-USA	6633

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LEXICON GENETICS INCORPORATED
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THE WOODLANDS, TX 77381-1160

EXAMINER

KELLY, ROBERT M

ART UNIT	PAPER NUMBER
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1632

9

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/060,069

Applicant(s)

ABUIN ET AL.

Examiner

Robert M Kelly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

1. Election was made **without** traverse in Paper No. 8. Claims 1-7 and 9 were cancelled.

Claim 8 is pending and explained herein.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

When determining whether an applicant has described the utility of invention, one has to determine whether the applicant has described a well-established utility. Well established utilities must be specific, substantial, and credible. In the absence of well established utility, the application is also looked to for any assertion by the Applicant of specific, substantial, and credible utilities. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for use. In contrast to general utility, a specific utility will be specific to the claimed subject matter. A substantial utility defines a real world utility of the invention; utilities that require or constitute carrying out further research to identify or reasonably confirm a real world use are not substantial utilities (see utility guidelines, Federal Register, January 5, 2001, Vol. 66, No. 5, pp. 1092-99).

The claimed embryonic stem cell line comprising an engineered mutation in at least one gene comprising a polynucleotide sequence first disclosed in one of SEQ ID NOS: 705 is not supported by a well established utility: such embryonic stem cells may be used for making

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comprising the engineered sequence. However, this is not a specific utility because the use of the cell line is generally applicable to any engineered embryonic stem cell line, and therefore the utility not particular to the sequence being claimed for that embryonic stem cell line. Moreover, the sequence itself does not provide for a specific utility, as the sequence disclosed is not known in any art of record or shown in the application to have any specific structural or functional properties. Therefore, no specific utility is found for the claimed subject matter.

With regard to substantial utility, the claimed stem cell line is not supported by a substantial utility because the specification states only that the stem cell lines are useful as probes for functionally characterizing the protein of interest. A starting material that can only be used to produce a final product does not have a substantial utility in those instances where the final product is not supported by a substantial utility. In this case the DNA sequence used to produce the protein of interest does not have an asserted or identified substantial utility. The research contemplated by Applicants to characterize potential protein products, especially their biological activities, does not constitute a substantial utility. Identifying and studying the properties of the protein itself or the mechanisms in which the protein is involved does not define a "real world" context of use.

Note because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein such that another non-asserted utility would be well established for the cell line.

Claim 8 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well

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established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, one of ordinary skill in the art at the time the invention was made was not enabled to make the claimed invention. Specifically, the claim is drawn to "An isolated murine embryonic stem cell..." which genus encompasses many species, including mice and rats. The specification further elaborates that the invention contemplates "animal(s) derived therefrom, that stably incorporates a gene trap vector..." (SPECIFICATION, p. 5). However, while mouse embryonic stem cells contribute to the germ line cells of the animal, such is not the case for rats. In fact, Buehr, et al. (2003) *Biology of Reproduction*, 68: 222-29 is a recent article that affirms there is no art existing that demonstrates rat embryonic stem cells can contribute to the germ line (ABSTRACT, "... appeared incapable of producing fetal germ layer derivatives.") Lastly, because SEQ ID NO. 705 was obtained from a mouse (SPECIFICATION, p. 6, lines 14-25). It was well known in the art at the time of the invention that sequences vary, even among strains of the same species, and there is no art of record that rats have the same sequence. Therefore, one of ordinary skill in the art at the time the invention was made would not have been enabled to make the claimed invention with respect to murine species except mice.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. The claim is drawn to sequences "first disclosed in...". It is unknown where or when else this sequence has been disclosed.

Furthermore, the claim is drawn to "an engineered mutation ... comprising a polynucleotide sequence ...". It is not known whether the sequence is the mutation or only comprises part of the mutation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (703) 305-4460. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.


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